

ACC INTERVENTIONAL SCIENTIFIC COUNCIL: NEWS AND VIEWS

2009 Focused Updates to Guidelines in ST-Elevation Myocardial Infarction and Percutaneous Coronary Intervention

Application to Interventional Cardiology

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Practice guidelines reflect a consensus of expert opinion for patient care after a thorough review of clinical trials relevant to a given patient population. However, in keeping pace with the influx of new data, these recommendations need to be revised periodically to remain current. The American College of Cardiology (ACC) and the American Heart Association (AHA) published the Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction in 2004 and the Guidelines for Percutaneous Coronary Intervention in 2005 with their respective Focused Updates in 2007. Now, 2 years later, further revision of these guidelines has been published as Focused Updates of 2009. (J Am Coll Cardiol Intv 2010; 3:256–8) © 2010 by the American College of Cardiology Foundation

The ACC and the AHA published the Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction (STEMI) in 2004 (1) and the Guidelines for Percutaneous Coronary Intervention (PCI) in 2005 (2). Subsequent clinical trial data prompted their respective focused updates in 2007 (3,4). Again, based on key clinical trials presented at the 2007 and 2008 annual scientific meetings of the ACC, AHA, Transcatheter Cardiovascular Therapeutics, European Society of Cardiology, and the 2009 annual scientific sessions of the ACC, the ACC/AHA Task Force on Practice Guidelines presented the 2009 Focused Updates of these guidelines (5). The revisions pertinent to interventional cardiology are reviewed here.

Use of Glycoprotein IIb/IIIa Receptor Antagonists

In the BRAVE-3 (Bavarian Reperfusion Alternatives Evaluation) study, patients presenting within 24 h

of STEMI were pretreated with clopidogrel 600 mg and then randomly assigned to receive either abciximab or placebo before being sent for PCI (6). At 30 days, the composite of death, recurrent myocardial infarction (MI), stroke, or urgent target vessel revascularization (TVR) was not significantly different between the glycoprotein (GP) IIb/IIIa receptor antagonist and placebo groups. In the On-TIME 2 (Ongoing Tirofiban In Myocardial Infarction Evaluation) study, patients were randomized to high-dose tirofiban or placebo in addition to unfractionated heparin (UFH) and clopidogrel within a median of 76 min from onset of symptoms (7). Although the tirofiban group had improved ST-segment resolution before and 1 h after PCI, there was no significant difference in death, recurrent MI, or urgent TVR between the 2 groups at 30 days. In the FINESSE (Facilitated Intervention with Enhanced Reperfusion Speed to Stop Events) study, patients with STEMI were randomized to half-dose fibrinolytic agent plus abciximab, pre-PCI abciximab, and abciximab at the time of PCI (8). After 90 days, there was no benefit and a trend toward excess bleeding with pre-hospital abciximab compared with abciximab at the time of PCI.

Based on these studies, the 2009 Focused Update recommends:

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Class IIa: It is reasonable to start treatment with GP IIb/IIIa receptor antagonists at the time of primary PCI in selected patients with STEMI.

Class IIb: The usefulness of GP IIb/IIIa receptor antagonists for patients with STEMI before their arrival in the catheterization laboratory for PCI is uncertain.

Use of Thienopyridines

The TRITON-TIMI 38 (Trial to Assess Improvement in Therapeutic Outcomes by Optimizing Platelet Inhibition With Prasugrel–Thrombolysis In Myocardial Infarction 38) trial randomly assigned patients with acute coronary syndrome treated with angioplasty and stent to receive prasugrel (60-mg loading dose and a 10-mg/day maintenance dose) or clopidogrel (300-mg loading dose and a 75-mg/day maintenance dose) for an average of 14.5 months (9). Prasugrel was associated with a significant reduction of stent thrombosis and of the composite of the rate of death due to cardiovascular causes, nonfatal MI, and nonfatal stroke.

Based on these findings, the 2009 Focused Update recommends:

Class I: A loading dose of 300- to 600-mg clopidogrel or 60-mg prasugrel should be given as soon as possible for STEMI patients for whom PCI is planned. The duration of therapy should be 75-mg clopidogrel or 10-mg prasugrel for at least 12 months in patients receiving a bare-metal stent (BMS) or drug-eluting stent (DES). The period of withdrawal of thienopyridine before coronary artery bypass grafting should be at least 5 days for clopidogrel and at least 7 days for prasugrel.

Class IIb: Continuation of clopidogrel or prasugrel beyond 15 months may be considered in patients undergoing DES placement.

Use of Parenteral Anticoagulants

In the HORIZONS-AMI (Harmonizing Outcomes With Revascularization and Stents in Acute Myocardial Infarction) trial, patients were randomized to treatment with UFH plus a GP IIb/IIIa receptor antagonist or to bivalirudin alone with provisional GP IIb/IIIa in addition to aspirin and a thienopyridine in both groups before cardiac catheterization and primary angioplasty (10). At 30 days, the rates of major bleeding and total adverse events were higher among patients treated with GP IIb/IIIa receptor antagonists and UFH than among those given bivalirudin alone. These data have included an all-cause survival advantage with bivalirudin.

Based on these findings, the 2009 Focused Update recommends:

Class I: For previous treatment with UFH, additional boluses of UFH should be administered as needed to maintain therapeutic activated clotting time levels. Bivaliru-

din is useful as a supportive measure for primary PCI with or without previous treatment with UFH.

Class IIa: In STEMI patients undergoing PCI who are at high risk of bleeding, bivalirudin anticoagulation is reasonable.

Thrombus Aspiration During PCI

The TAPAS (Thrombus Aspiration During Percutaneous Coronary Intervention in Acute Myocardial Infarction Study) randomized STEMI patients to manual thrombus aspiration before PCI or conventional PCI with balloon angioplasty followed by stenting (11). At 1 year, the rates of cardiac death and nonfatal reinfarction were lower with thrombus aspiration. The EXPIRA (Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention) trial compared thrombus aspiration with conventional PCI in patients with thrombolysis in myocardial infarction flow 0/1 and found that infarct size was significantly reduced at 3 months only in the thrombus aspiration group (12).

Based on these studies, the 2009 Focused Update recommends:

Class IIa: Aspiration thrombectomy is reasonable for patients undergoing primary PCI.

Stents in STEMI

The randomized trial HORIZONS-AMI showed no difference in 12-month death, reinfarction, stroke, or stent thrombosis between DES and BMS (13). Two-year data from the Massachusetts registry comparing matched pairs of DES and BMS patients demonstrated a reduction in mortality and TVR rates with DES in primary PCI (14). Another registry from New York State found a reduction in the mortality rate but not the TVR rate with DES (15). Meta-analyses of multiple small randomized clinical trials have shown no differences between BMS and DES in mortality rate, MI rate, or stent thrombosis risk (16–18).

Based on these studies, the 2009 Focused Update recommends:

Class IIa: It is reasonable to use a DES as an alternative to a BMS for primary PCI in STEMI.

Class IIb: A DES may be considered for clinical and anatomic settings in which the efficacy/safety profile seems favorable.

Use of Fractional Flow Reserve

The FAME (Fractional Flow Reserve Versus Angiography for Guiding PCI in Patients With Multivessel Coronary Artery Disease) trial compared clinical outcomes after PCI on the basis of conventional angiographic determination of lesion severity versus fractional flow reserve (FFR) com-

bined with angiography in patients with multivessel disease (19). At 1 year, the composite event rate of death, nonfatal MI, and TVR was significantly lower in the FFR-guided group.

Based on this study, the 2009 Focused Update recommends:

Class IIa: FFR can be useful to determine whether PCI of a specific coronary lesion is warranted. FFR can also be useful as an alternative to performing noninvasive functional testing to determine whether intervention is warranted. FFR is reasonable for the assessment of intermediate coronary stenoses in patients with anginal symptoms.

Class III: Routine assessment with FFR or Doppler ultrasonography to assess severity of angiographic disease in patients with angina and a positive unequivocal noninvasive functional study in concordant vascular distribution is not recommended.

PCI for Unprotected Left Main Coronary Artery Disease

The SYNTAX (TAXUS Drug-Eluting Stent Versus Coronary Artery Bypass Surgery for the Treatment of Narrowed Arteries) clinical trial randomized patients with 3-vessel and/or left main coronary artery disease to an initial treatment strategy of coronary artery bypass graft or PCI (20). Within the subgroup of patients with left main coronary artery disease, there were no significant differences in the incidence of the composite end point of death, MI, stroke, or TVR between the 2 groups. Although the rates of TVR were higher, the rates of stroke were lower in the PCI group. A white paper produced under the auspices of the Interventional Scientific Council addressed this subject comprehensively (21).

Based on these findings, the 2009 Focused Update recommends:

Class IIb: PCI of the left main coronary artery with stents as an alternative to coronary artery bypass graft may be considered in patients with anatomic conditions that are associated with a low risk of PCI procedural complications and clinical conditions that predict an increased risk of adverse surgical outcomes.

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